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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/017,568 | 12/14/2001 | Michael B. Zemel | UTR-104C1 | 9941 |
| 26694 | 7590 | 12/29/2005 | EXAMINER | |
| VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20045-9998 | | | WEBMAN, EDWARD J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | |
| DATE MAILED: 12/29/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/017,568 | Applicant(s) ZEMEL ET AL. | |
| | Examiner Edward J. Webman | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-27, 29 and 35-68 is/are pending in the application.
- 4a) Of the above claim(s) 22, 25-27, 29, 42-49, 51-54, 59, 60, 62 and 64-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21, 23, 24, 35-41, 50, 55-58, 61 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/1/04, 9/10/04, 5/27/05, 8/04/05</u> | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of a method of regulating body weight, a chemical compound binding to the 1,25-(OH)₂-D receptor, blocking an increase intracellular calcium concentration, reducing the risk of heart disease, reducing intracellular calcium concentration in the reply filed on 9/10/04 and clarification by telephone on 12/15/05 is acknowledged. The traversal is on the ground(s) that burden, including number of species, and distinctness have not been shown. This is not found persuasive because for an election of species distinctness need be shown. If applicants state on the record that the species are not distinct, the election of species will be withdrawn, however, an art rejection over one shall be applicable to all. As to the asserted small number of species, the assertion is mere opinion.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 23-24, 35-41, 50, 53, 55-58, 61, 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shi et al (FASEB J., 12/2001, v. 15, p. 2751) in view of Norman et al (JBC 11/25/98, v. 508(27), p. 20022).

Shi et al teach that 1 alpha, 25-dihydroxyvitamin D₃ induces an increase in calcium ion concentration in adipocytes and a concomitant inhibition of lipolysis by binding to a putative vitamin D receptor on the cell membrane (title, principal findings 1. and 2. p. 2751).

Norman et al teach that 1 beta, 25-dihydroxyvitamin D3 is an antagonist of the 1 alpha compound, particularly calcium ion uptake (title, 2nd para. in abstract).

It would have been obvious to one of ordinary skill to use the 1 beta compound to control weight in view of the fact that Shi et al teach that the 1, alpha compound inhibits lipolysis and that the beta compound blocks the action of the alpha compound by binding to vitamin D receptors regulating calcium ion uptake. One of ordinary skill would recognize that blocking 1, alpha compound will promote lipolysis and, therefore, weight loss. As to the claimed reduction in risk of coronary artery disease, one of ordinary skill, in fact, even a layman, will recognize that weight loss will reduce the risk of said disease. As to the claimed liquid vehicle, an alcoholic would be an obvious expedient in view of the multiple hydroxyl groups carried by the compound.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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